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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,537	06/19/2000	LESLIE LARS IVERSEN	P24.002USA	9631

7590 06/14/2004

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/14/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,537

Applicant(s)

IVERSEN, LESLIE LARS

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 21-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 21-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The request filed on 4/17/2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/529537 is acceptable and a CPA has been established. An action on the CPA follows.

Specification

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper (See Specification at pages 5-7). Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 179 USPQ 167 (CCPA 1973). The claims are directed to CCK antagonists, as such, the description of CCK antagonists in the Specification constitutes essential material.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,21-28, 30-44 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1,2,21-28, 30-44 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 11 filed 7/22/2002. In that paper, applicant has stated the opioid is present in the hydrophilic phase and the CCK antagonist is present in the organic phase,

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and this statement indicates that the invention is different from what is defined in the claim(s) because the claims do not indicate the same.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 21-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1 564 039 in view of Patel et al. and EP 0 391 369 in further view of Woodruff et al. (Abstract). and Dappen et al. (U.S. Pat. 5,223,507) for the reasons of record and the further reasons below.

GB 1 564 039, Patel et al. and EP 0 391 369 were discussed in the prior Office Action and the same are incorporated herein.

Woodruff et al. teach that that benzodiazepines, including flurazepam, diazepam, lorazepam, chlordiazepoxide, medazepm, devazepide, L-356260, L-365031, are CCK antagonists (Abstract).

Dappen et al. teaches that gelatin, alginates, cross linked carboxy methyl cellulose and other celluloses, PVP, lactose and other non-toxic compatible substances are suitable excipients for pharmaceutical dosage forms containing opioids (Columns 25-29, Column 30, lines 1-36).

Examiner has duly considered Applicant arguments but deems them unpersuasive.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 18 USPQ2d 1885

(Fed. Cir. 1991). Further, Applicant has not cited to any statute, rule or caselaw which establishes disparate publication dates as being relevant to the issue of obviousness. The references applied in the rejection herein all were published prior to the effective filing date, and, thus, are valid prior art.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Contrary to Applicant's arguments that combined teachings of the prior art would motivate one of ordinary skill in the art to arrive at the claimed invention. The prior art teaches the combination of CCK antagonists and opioids. Further, oil-in-water pharmaceutical preparations are taught by the prior art. Furthermore, one of ordinary skill in the art would expect that poorly water soluble drugs would be carried by the organic phase whereas water soluble drugs would be carried by the aqueous phase. As such, one of ordinary skill in the art would expect that water-soluble opioids would be carried in the aqueous phase and that poorly water soluble CCK antagonists would be carried by the organic phase of a oil-in-water preparation.

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Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

June 9, 2004



JOHN PAK
PRIMARY EXAMINER
GROUP 1600